



Handwritten signature/initials

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sudhir V. Shah
Application No.: 10/731,521 Group Art Unit: 1645
Filed: December 9, 2003 Examiner: Not Assigned
Confirmation No.: 3717
Title: DIAGNOSIS AND TREATMENT OF HUMAN KIDNEY DISEASES

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
<u>6/15/04</u> Date	<u>Jennifer Warner</u> Signature
<u>Jennifer Warner</u> Typed or printed name of person signing certificate	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☐ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☒ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☒ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

06/18/2004 HUJ061 00000031 10731521 180.00 0P
01 FC:1806

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references are enclosed. (AW5, AX5)
 - ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. 09/553,496, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
 - ☒ Previously cited references (AL-AO, AY3, AZ3, AR4) were cited in the enclosed International Search Report in a related foreign application.
 - ☐ The "concise explanation" requirement (non-English references) for reference(s) under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstracts.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. 10/820,478, by Sudhir V. Shah, filed April 8, 2004, Docket No.: 2629.1003-008
____ U.S. Patent Application No. 10/731,522, by Sudhir V. Shah, filed December 9, 2003, Docket No.: 2629.1003-009
____ U.S. Patent Application No. 10/820,537, by Sudhir V. Shah, filed April 8, 2004, Docket No.: 2629.1003-011

Examiner

Date

- [X] A copy of each above-cited application, including the current claims, is enclosed.
- [] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- [X] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- [] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Mary K. Murray
Mary K. Murray
Registration No.: 47,813
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: June 15, 2004

PTO-1449 REPRODUCED SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION June 15, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2629.1003-010	APPLICATION NO. 10/731,521	
	FIRST NAMED INVENTOR Sudhir V. Shah		FILING DATE December 9, 2003
	EXAMINER Not Assigned	CONFIRMATION NO. 3717	GROUP 1645

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AE	5,091,180	02-25-1992	Walker et al.
	AF	5,047,329	09-10-1991	Suzuki

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AS4	Walker, P.D., et al., "Evidence Suggesting a Role for Hydroxyl Radical in Gentamicin-Induced Acute Renal Failure in Rats," <i>J Clin Invest</i> 81:334-341 (1988).
AT4	Shah, S.V., et al., "Evidence Suggesting a Role for Hydroxyl Radical in Glycerol-Induced Acute Renal Failure," <i>Am J Physiol</i> 255, (Renal Fluid Electrolyte Physiol. 24):F438-F443 (1988).
AU4	Baliga, R., et al., "Increase in Bleomycin-Detectable Iron in Ischaemia/Reperfusion Injury to Rat Kidneys," <i>Biochem J</i> 291(3):901-905 (1993).
AV4	Kontoghiorghese, G.J., et al., "Studies of Aluminium Mobilization in Renal Dialysis Patients Using the Oral Chelator 1,2-Dimethyl-3-hydroxypyrid-4-one," <i>Arzneim-Forsch/Drug Res.</i> 44(1):522-526 (1994).
AW4	Baliga, R., et al., "Oxidant Mechanisms in Toxic Acute Renal Failure," <i>Drug Metabolism Reviews</i> 31(4):971-991 (1999).
AX4	Walker, P.D., et al., "Gentamicin Enhanced Production of Hydrogen Peroxide by Renal Cortical Mitochondria," <i>Am J Physiol</i> 253:C495-C499 (1987).
AY4	Walker, P.D., et al., "Hydrogen Peroxide Cytotoxicity in LLC-PK ₁ Cells: A Role for Iron," <i>Kidney Int</i> 40:891-898 (1991).
AZ4	Abul-Ezz, S.R., et al., "Role of Glutathione in an Animal Model of Myoglobinuric Acute Renal Failure," <i>Proc Natl Acad Sci</i> 88:9833-9837 (1991).
AR5	Ueda, N., et al., "Gentamicin-Induced Mobilization of Iron from Renal Cortical Mitochondria," <i>Am J Physiol</i> 265(3 Pt. 2):F435-F439 (1993).
AS5	Baliga, R., et al., "Evidence for Cytochrome P-450 as a Source of Catalytic Iron in Myoglobinuric Acute Renal Failure," <i>Kidney Int</i> 49:362-369 (1996).

EXAMINER	DATE CONSIDERED
----------	-----------------

PTO-1449 REPRODUCED SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION June 15, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2629.1003-010	APPLICATION NO. 10/731,521	
	FIRST NAMED INVENTOR Sudhir V. Shah		FILING DATE December 9, 2003
	EXAMINER Not Assigned	CONFIRMATION NO. 3717	GROUP 1645

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AT5		Baliga, R., <i>et al.</i> , "Role of Cytochrome P-450 as a Source of Catalytic Iron in Cisplatin-Induced Nephrotoxicity," <i>Kidney Int</i> 54:1562-1569 (1998).
AUS		Hanss, B.G., <i>et al.</i> , "The Iron Chelator Deferoxamine Prevents Contrast Media Induced Acute Renal Failure in the Rabbit." Presented at the American Society of Nephrology, 23 rd Annual Meeting, <i>JASN</i> 1(4):612 (1990) (abstract).
AV5		Baliga, R., <i>et al.</i> , "Role of Iron in Cisplatin-Induced Acute Renal Failure in Rats," <i>J Am Soc Nephrol</i> 7(9):1822 (1996) (abstract).
AWS		Fernández-Real, J.M., <i>et al.</i> , "Cross-Talk Between Iron Metabolism and Diabetes," <i>Diabetes</i> , 51:2348-2354, 2002
AX5		Nitenberg, A., <i>et al.</i> , "Coronary Microvascular Adaptation to Myocardial Metabolic Demand Can Be Restored by Inhibition of Iron-Catalyzed Formation of Oxygen Free Radicals in Type 2 Diabetic Patients," <i>Diabetes</i> , 51:813-818, 2002

* → these are the only documents that I found.

EXAMINER	DATE CONSIDERED
----------	-----------------